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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/074,472	05/07/98	RICHTER M	33746200600

HM12/0606

EXAMINER
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ART UNIT	PAPER NUMBER
1655	26

DATE MAILED: 06/06/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

1- File Copy

Office Action Summary

Application No.	Applicant(s)
09/074,472	Richter et al
Examiner	**Art Unit**
Arun Chakrabarti	1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on May 11, 2001.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 28 and 29 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 28 and 29 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CAR 1.114, including the fee set forth in 37 CAR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CAR 1.114, and the fee set forth in 37 CAR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CAR 1.114. Applicant's submission filed on May 11, 2001, has been entered.

Specification

2. Claims 1-23 and 25-27 have been canceled without prejudice towards further prosecution and new claims 28-29 have been added.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 28 is rejected under 35 U.S.C. 103 (a) as being unpatentable over Aizawa et al. (Proceedings of Electrochemical Society (1993), Vol. 93-7, pages 662-73) in view of Tyagi et al. (U.S. Patent 5,925,517) (July 20, 1999)

Aizawa et al. teach a method for detecting quantitatively an analyte in a sample composition (abstract) comprising the steps of:

(a) preparing an assay mixture comprising: said sample composition; a reagent having an ECL label (Abstract);

(b) determining any difference between the ECL emissions of: (I) the assay mixture prepared in step (a); and, (ii) an assay mixture comprising: said reagent having an ECL label; and a known amount of said analyte; and, c) correlating any difference determined in step (b) with the amount of analyte in said sample (Electrochemiluminescence Immunosensing Section and Figures 2 and 6).

Aizawa et al. teach a method wherein said ECL label comprises a polyaromatic hydrocarbon (Figure 7).

Aizawa et al. teach a method wherein said ECL label comprises Ruthenium or Osmium (Figure 7).

Aizawa et al. teach the method wherein said analyte comprises an oligonucleotide (DNA or RNA), polypeptide, antibody, antigen, an enzyme, an enzyme substrate, polysaccharide.

Aizawa et al. teach a method wherein known amount of analyte is zero (Figures 6 and 11).

Aizawa et al do not teach a method wherein reagent having an ECL quenching moiety, said ECL quenching moiety comprising at least one benzene moiety; said ECL quenching moiety comprises at least one moiety selected from the group consisting of phenol moieties, quinone moieties, benzene carboxylic acid moieties, and benzene carboxylate moieties.

Aizawa et al do not teach a method wherein said reagent having an ECL label and said reagent having an ECL quenching moiety are either same or different reagent.

Tyagi et al. teach the method wherein the quenching moiety comprises at least one phenol moiety, at least one benzene carboxylic acid moiety or at least one benzene carboxylate moieties (Abstract and column 16, lines 23 to column 17, line 3 and Figure 3). Fluorescein, the quenching label, has at least two benzene moieties.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to include the group of chemicals containing substituted benzene rings of Tyagi et al. in the method of Aizawa et al., since Tyagi et al. state, "By using multiple probes with interactive labels that generate different, non-interfering detectable signals, e.g., fluorescence at different wavelengths or fluorescence and colored product formation, assays of this invention can detect multiple targets in a single assay (Column 21, lines 24-28)." An ordinary practitioner would have been motivated to combine and compare the

electrochemiluminescence quenching chemicals containing deferentially substituted benzene ring of Tyagi et al. into the method of Aizawa et al. in order to achieve the express advantages, as noted by Tyagi et al., of electrochemiluminescence quenching chemicals which provide detection of multiple targets in a single assay.

5. Claims 28-29 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Aizawa et al. (Proceedings of Electrochemical Society (1993), Vol. 93-7, pages 662-73) in view of Tyagi et al. (U.S. Patent 5,925,517) (July 20, 1999) further in view of Stratagene Catalog (1988, Page 39).

Aizawa et al in view of Tyagi et al. expressly teach the method claims and assay reagents of 28 as described above in detail.

Aizawa et al in view of Tyagi et al. does not teach the motivation to combine all the reagents for detecting an analyte in a sample in the form of a kit.

Stratagene catalog teaches a motivation to combine reagents into kit format (page 39).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine a suitable container, ECL label and ECL quenching moiety of Aizawa et al in view of Tyagi et al. into a kit format as discussed by Stratagene catalog since the Stratagene catalog teaches a motivation for combining reagents of use in an assay into a kit, "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. Thus one need not purchase gram quantities of 10 different reagents, each of which is needed in only microgram amounts, when beginning a series of experiments. When one considers all of the unused chemicals that typically accumulate in weighing rooms, desiccators, and freezers, one quickly realizes that it is actually far more

expensive for a small number of users to prepare most buffer solutions from the basic reagents. Stratagene provides only the quantities you will actually need, premixed and tested. In actuality, the kit format saves money and resources for everyone by dramatically reducing waste. 2) The other service provided in a kit is quality control (page 39, column 1).

Response to Amendment

6. In view of the amendment, 112 (first paragraph) rejections are withdrawn. However, other 103 rejections are hereby being maintained because of the following reason. The applicant has deleted all previously rejected claims and added two new claims with all the limitations of rejected dependent claims. Applicant is hereby advised that same rejections as made in the last office action is appropriately being maintained.

Response to Arguments

7. Applicant's arguments filed on May 11, 2001, have been fully considered but they are not persuasive. Applicant argues that Tyagi et al do not teach electrochemiluminescence quencher and teach only fluorescence quencher. This argument is not persuasive. Tyagi et al clearly teach electrochemiluminescence quencher (Column 16, lines 23-33). In view of the response to arguments, all 103 rejections are hereby being maintained.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703)

306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Arun Kr. Chakrabarti

Arun Chakrabarti,

Patent Examiner,

May 28, 2001

JEFFREY FREDMAN
PRIMARY EXAMINER